Director, Clinical Development/Study Clinician

Lexington, MA

About Us: At Nightstar, our mission is to maintain and restore sight in patients with inherited retinal diseases. We are a clinical-stage company focused on developing and commercializing a pipeline of novel and potentially curative, one-time retinal gene therapies for patients suffering from rare inherited retinal diseases that would otherwise progress to blindness, and, for which, there are no currently approved treatments.

Job Purpose: We are seeking a Director, Clinical Development for the Company's Lexington, MA office. The Director, Clinical Development work on providing drug development experience to bring forward programs into the clinic and develop these in the earlier phases of clinical development

Job Responsibilities:

- Work to bring forward programs into the clinic
- Awareness and ability to link the late stage preclinical programs with what would be needed in the clinic
- Help formulate and provide input into early phase clinical development programs, including recommendation of primary and secondary end points, biomarkers and inclusion/exclusion criteria with the view of gaining regulatory approval
- Direct all aspects of activities relating to: preparation of protocols, clinical trials, data analyses and written study reports, including being the medical monitor for clinical trials
- Communication and ability to form strong relationships with Ophthalmology KOLs
- Collaborate with study teams to ensure that the clinical aspects of protocol are properly executed
- Oversee feasibility assessment and investigator/site selection
- Interact with CRO and other vendor relationships
- Manage and assist with Competent Authority and Ethics Committee/IRB submissions

Critical Competencies:

- Expert knowledge of early phase clinical trial approval processes and international guidelines and regulations
- Professional credentials as a physician (MD) or equivalent (e.g. PhD, OD)
- Significant experience of early clinical development, Phase 1/2
- Experience in ophthalmology preferred
- Experience in running gene therapy trials preferred
- Experience in leading and managing project teams and managing multiple projects concurrently.
- Thorough knowledge of clinical trial approval processes including a strong grasp of international guidelines and regulations (FDA, ICH, and GCP)
- Strong understanding of budget management

Behavioral and Interpersonal:

- Excellent oral and written communication skills as well as the ability to facilitate analysis and problem solving through the effective facilitation of group activities
- Strong organizational and time management skills including the ability to function effectively in a team environment
- Demonstrated professionalism and adherence to high ethical standards
- Demonstrated ability to manage multiple priorities to achieve results and meet milestones in a “hands- on” fashion.